Amendments to the Claims

1. (currently amended): A stable liquid formulation of a therapeutically active protein ~~useful for aerosol delivery to the respiratory tract of a patient in need of treatment~~ comprising:

(a) a carrier liquid consisting essentially of from about 10% v/v to ~~from~~ about 100% v/v water and from about 0% to from about 90% v/v of an organic liquid;

(b) a biologically effective amount of said protein suspended or dissolved in said carrier liquid; and

(c) a stabilizing effective amount of a stabilizing component consisting of a derivatized carbohydrate ~~stabilizing agent~~ suspended or dissolved in said carrier liquid;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5 or 6 and wherein said hydrocarbon group contains about 6 to about 18 carbon atoms which may be straight chain or branched chain, and wherein said therapeutically active protein is not an enzyme.

2. (previously presented): A stable formulation according to claim 1 wherein said formulation contains from about 0.1% w/v to about 5.0% w/v of a pharmaceutically acceptable excipient.

3. (currently amended): A stable formulation according to claim 1 wherein said therapeutically active protein is selected from the group ~~comprising~~ consisting of antibodies, antigens, hormones and cytokines.

4. (original): A stable formulation according to claim 3 wherein said therapeutically active protein is a hormone.

5. (original): A stable formulation according to claim 4 wherein said therapeutically active protein is insulin.

6. (original): A stable formulation according to claim 3 wherein said therapeutically active protein is a cytokine.

7. (currently amended): A stable liquid formulation ~~according to claim 6 wherein said~~ of a therapeutically active protein comprising:

(a) a carrier liquid consisting essentially of from about 10% v/v to about 100% v/v water and from about 0% to from about 90% v/v of an organic liquid;

(b) a biologically effective amount of said protein suspended or dissolved in said carrier liquid; and

(c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent suspended or dissolved in said carrier liquid;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5 or 6 and wherein said hydrocarbon group contains from about 6 to about 18 carbon atoms which may be straight chain or branched chain, and wherein said therapeutically active protein is Factor VIII.

8. (previously presented): A stable formulation according to claim 1 wherein said carrier liquid contains from about 20% v/v to from about 100% v/v water.

9. (previously presented): A stable formulation according to claim 8 wherein said carrier liquid comprises about 50% v/v water and about 50% v/v organic solvent.

10. (currently amended): A stable formulation ~~according to claim 1 wherein said organic liquid is~~ of a therapeutically active protein comprising:

(a) a carrier liquid consisting essentially of from about 10% v/v to about 100% v/v water and from about 0% to about 90% v/v of an organic liquid selected from the group consisting of ethanol, isopropyl alcohol, butanol, isobutanol, perfluorocarbons, glycerol, polyethylene glycol, propylene glycol, ~~or combinations~~ and mixtures thereof;

(b) a biologically effective amount of said protein suspended or dissolved in said carrier liquid; and

(c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent suspended or dissolved in said carrier liquid;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5 or 6 and wherein said hydrocarbon group contains from about 6 to about 18 carbon atoms which may be straight chain or branched chain, and wherein said therapeutically active protein is not an enzyme.

11. (currently amended): A stable formulation according to claim 10 wherein said organic liquid is selected from the group consisting of ethanol, glycerol, polyethylene glycol propylene glycol, ~~or combinations~~ and mixtures thereof.

12. (currently amended): A stable liquid formulation ~~according to claim 1 wherein said derivatized carbohydrate~~ of a therapeutically active protein comprising:

a) a carrier liquid consisting essentially of from about 10% v/v to about 100% v/v water and from about 0% to about 90% v/v of an organic liquid;

(b) a biologically effective amount of said protein suspended or dissolved in said carrier liquid; and

(c) a stabilizing effective amount of a derivatized hydrocarbon stabilizing agent suspended or dissolved in said carrier liquid;

wherein said stabilizing agent is selected from the group consisting of C8-trehalose, ~~and~~ C8-glycopyranoside, and mixtures thereof, and wherein said therapeutically active protein is not an enzyme.

13. (currently amended): A stable liquid formulation ~~according to claim 1 wherein said protein is suspended in the~~ of a therapeutically active protein comprising:

(a) a carrier liquid consisting essentially of from about 10% v/v to about 100% v/v water and from about 0% to about 90% v/v of an organic liquid;

(b) a biologically effective amount of said protein suspended in said carrier liquid; and

(c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent suspended or dissolved in said liquid carrier;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5 or 6 and wherein said hydrocarbon group contains from about 6 to about 18 carbon atoms which

may be straight chain or branched chain, and wherein said therapeutically active protein is not an enzyme.

14. (original): A stable formulation according to claim 13 wherein the particle size of said protein in suspension is from about 0.01 μ to about 10.0 μ.

15. (original): A stable formulation according to claim 14 wherein the particle size of said protein in suspension is from about 5.0 μ to about 10.0 μ.

16. (original): A stable formulation according to claim 15 wherein the particle size of said protein in suspension is from about 0.1 μ to about 3.0 μ.

17. (original): A stable formulation according to claim 2 wherein said formulation contains from about 0.1% to about 5.0% of a pharmaceutically acceptable excipient.

18. (original): A stable formulation according to claim 1 wherein said protein is dissolved in the carrier liquid.

19. (previously presented): A stable formulation according to claim 18 wherein said formulation contains from about 0.1% w/v to about 5.0% w/v of a pharmaceutically acceptable excipient.

20. (currently amended): A method of formulating a stable liquid formulation of a therapeutically active protein useful for aerosol delivery to the lower respiratory tract of a patient in need of treatment comprising the mixing of components comprising:

(a) a carrier liquid which consists essentially of from about 10% v/v to from about 100% v/v water and from about 0% v/v to from about 90% v/v ethanol;

(b) a biologically effective amount of said protein suspended or dissolved in said carrier liquid; and

(c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5, or 6 and wherein said hydrocarbon group contains about 6 to 18 carbon atoms which may be straight chain or branched chain, and wherein said therapeutically active protein is not an enzyme.

21.–22. Canceled.

23. (new): An apparatus for delivery of a therapeutically active protein to the lower respiratory tract of a patient comprising an electrostatic or an electrohydrodynamic device capable of generating inhalable aerosols, said device containing a stable liquid formulation of a therapeutically active protein comprising:

(a) a carrier liquid consisting essentially of from about 10% v/v to about 100% v/v water and from about 0% to about 90% v/v of an organic liquid;

(b) a biologically effective amount of said protein suspended or dissolved in said carrier liquid; and

(c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent suspended or dissolved in said carrier liquid;

wherein said derivatized carbohydrate comprises a sugar moiety selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose modified by the addition of at least one alkyl or alkenyl hydrocarbon group attached to said sugar moiety at carbon 1, 2, 3, 4, 5 or 6 and wherein said hydrocarbon group contains about 6 to about 18 carbon atoms which may

be straight chain or branched chain, and wherein said therapeutically active protein is not an enzyme.